

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In Re Application of:**

**Oliver Neckebroek, et al.**

**Application No.: 10/539,918**

**Filing Date: February 17, 2006**

**For: PROCESS FOR THE PREPARATION OF AND CRYSTALLINE FORMS OF  
OPTICAL ENANTIOMERS OF MODAFINIL**

**Confirmation No.: 8401**

**Group Art Unit: Not Yet Assigned**

**Examiner: Not Yet Assigned**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or

before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

- ☐ Certification in Accordance with § 1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☒ Copies of reference numbers **1 – 13 and 21-25** listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of reference numbers **14 – 20** on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

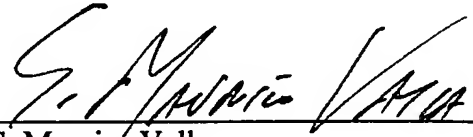
- ☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

- ☐ The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

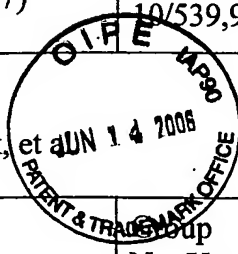
Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: June 7, 2006

  
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. CEPF-0006 (CP247)	Application No. 10/539,918
	Applicant Oliver Neckebroek, et al	
	Filing Date February 17, 2006	Not Yet Assigned
	Confirmation No. 8401	

**NON-PATENT DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	1	Amiard, G., "No. 81.-Sur le dédoublement direct de la thréonine, par entraînement," <i>Bull. Soc. Chim. Fr.</i> , <b>1956</b> , 447 (no English abstract)
	2	Armodafinil Search, "Preliminary results from registry number search," April 10, <b>2006</b> , 1-36 and 1-296
	3	Bernstein, J., "Polymorphism in molecular crystals," <i>University Press, UK</i> , <b>2002</b> , Chapter 10, 297-307
	4	Coquerel, G., "Review on the heterogeneous equilibria between condensed phases in binary systems of enantiomers," <i>Enantiomers, Gordon &amp; Breach Science Publishers</i> , <b>2000</b> , 5, 481-498
	5	Collet, A., et al., "Optical resolution by direct crystallization of enantiomer mixtures," <i>Chem. Rev.</i> , <b>1980</b> , 80(3), 215-230
	6	Courvoisier, L., et al., "Influence of the process on the mechanisms and the performances of the preferential crystallization: example with (±)-5-4(4-Bromophenyl)-5-methylhydantoin," <i>Chemistry Letters</i> , <b>2001</b> , 364-365
	7	De Min., M., et al., "Chiral resolutions, asymmetric synthesis and amplification of enantiomeric excess," <i>J. Chem. Phys.</i> , <b>1988</b> , 85, 603-619
	8	Donovan, J.L., et al., "Chiral analysis of <i>d</i> - and <i>l</i> -modafinil in human serum: application to human pharmacokinetic studies," <i>Ther. Drug Monitoring</i> , <b>2003</b> , 25, 197-202
	9	In, Y., et al., "Crystal and molecular structure of an (S)-(+)-enantiomer of modafinil, a novel wake-promoting agent," <i>Chem. Pharm. Bull.</i> , <b>2004</b> , 52(10), 1186-1189
	10	Kim, S., et al., "A simple and mild esterification method for carboxylic acids using mixed carboxylic-carbonic anhydrides," <i>Am. Chem. Soc.</i> , <b>1985</b> , 560-565
	11	Ndzié, E., et al., "An efficient access to the enantiomers of $\alpha$ -methyl-4-carboxyphenylglycine via a hydantoin route using a practical variant of preferential crystallization AS3PC (auto seeded programmed polythermic preferential crystallization)," <i>Tetrahedron Asymmetry</i> , <b>1997</b> , 8(17), 2913-2920
	12	Prisinzano, T., et al., "Synthesis and determination of the absolute configuration of the enantiomers of modafinil," <i>Tetrahedron: Asymmetry</i> , <b>2004</b> , 15, 1053-058
	13	Raynal, H., et al., "Disposition of modafinil enantiomers in humans and dogs," <i>ISSX Proceedings, Fifth European ISSX Meeting, Tours, France</i> , September 26-29, <b>1993</b> , 1 page

EXAMINER

DATE CONSIDERED

**Form PTO-1449 Modified**Docket No.  
CEPF-0006 (CP247)Application No.  
10/539,918List of Patent and Publications  
Cited by Applicant  
(Use several sheets if necessary)Applicant  
Oliver Neckebroek, et al.U.S. Department of Commerce  
Patent and Trademark OfficeFiling Date  
February 17, 2006Group  
Not Yet AssignedConfirmation No.  
8401**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	14	4,177,290	12/04/79	Lafon	424	324
	15	4,927,855	05/22/90	Lafon	514	618
	16	6,489,363 B2	12/03/02	Jacobs, et al.	514	615
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	20	2004/0048931 A1	03/11/04	Heacock, et al.	514	629

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## U. S. PATENT DOCUMENTS

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### FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	21	WO2001/022961 A1 ✓	04/05/01	PCT	X abstract ✓	
	22	WO 02/10125 A1 ✓	02/07/02	PCT		
	23	WO2004/060858 A1 ✓	07/22/04	PCT	X abstract ✓	
	24	0 720 595 B1 ✓	12/23/98	EP	X abstract ✓	
	25	1 197 809 ✓	07/08/70	GB		

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